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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary

Application No.

10/822,559

Applicant(s)

BELLO ET AL.

Examiner

NEAL R. SEREBOFF

Art Unit

3626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37, 39-49, 51-54, 57-62, 64-66, 68-91 and 93-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37, 39-49, 51-54, 57-62, 64-66, 68-91 and 93-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. In the amendment dated 6/16/2009, the following has occurred: Claims 1 – 3, 9, 10, 15, 27, 49, 51, 54, 59, 62, 64, 65, 68, 70, 71, 76, 78, 80, 82, 84, 86, 88, 90, 93, 95 and 101 have been amended; Claims 38, 50, 55, 56, 63 and 67 have been canceled.
2. Claims 1 – 37, 39 – 49, 51 – 54, 57 – 62, 64 – 66, 68 – 91 and 93 – 101 are pending.
3. The Applicant states that he has replaced the paragraph beginning at page 1, line 16 of the application. The Examiner believes that the Applicant intended to replace the similar paragraph found on page 73, line 24. The Examiner makes this understanding in that the first 3 lines of the replacement paragraph and the first 3 lines of the paragraph found on page 73 are the same. Therefore, in the interest of furthering prosecution, the Examiner feels that this adjusted replacement is clear.

Notice to Applicant

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

5. The Applicant has claimed priority to multiple provisional and non-provisional applications. It is not clear from the priority claim whether the claimed invention should receive priority from any of the cited applications. The Examiner notes that the Applicant's claims priority through continuation in part to 10 previous U.S. patent applications. The Examiner does not understand how the claimed invention should receive priority to any of these prior applications. In addition, the Examiner is unsure what the Applicant means by "relates to" as

this could be understood that these were created by the same inventors but regards a completely different topic. Therefore, in the interest of furthering prosecution, the Examiner is applying art that predates the earliest publication date. However, this should not be construed as an acknowledgement of prior priority.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "Line Set" as described within Pre-Grant Publication paragraph 647. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The Examiner is unsure what parts of figures 1, 3 and 53 the Applicant considers a "line set." The specification page 140, line 18 through page 141, line 6 states, "The system also has a plurality of medical devices 120, which, as mentioned, can be a controller for a medical device, such as a controller for an infusion pump, or can be a pumping mechanism, such as a MEMS pump *integral with a line set* (see FIGS. 1, 3, and 53), as well as other types of medical devices." (emphasis added) There is nothing within the drawings that show what a line set is.

The Applicant's Specification amendment, as understood above, includes the change, "Preferably, the pump element 5314 generates the fluid flow through a tube which is part of line set 5312 based on information stored locally within the MEMS electronics 5332." The Applicant's amendment does not clarify what in the drawings makes up a line set as described. For example, what else is part of the line set? The Applicant's amendment implies that there are other components that are part of the line set.

Claim Objections

7. Claim 93 is objected to because of the following informalities: Claim 92 was canceled but claim 93 still depends upon claim 92. The Examiner understands that claim 93, like claim 68, depends upon the respective independent claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 49 and 62 – 64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 49 and 62 – 64 are rejected under 35 U.S.C. 101 based on Supreme Court precedent, and recent Federal Circuit decisions, a § 101 process must (1) be tied to a machine (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. In re Bilski, F.3d, 88 U.S.P.Q.2d 1385 (2008). Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876). The process steps in claims

(49 and 62 – 64) are not tied to a machine nor do they execute a transformation. Thus, they are non-statutory.

It is not clear from the claims whether there is a machine that is “causing the first central computer to” perform various tasks. This “causing” function could be performed by a human in which case the computer only performs incidental extra solution activities. If the “causing” is performed by a machine, the computer is still performing extra solution activities; the determination regarding which tasks to be transmitted is not a machine controlled process.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 2, 7, 9, 10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Regarding claims 2, 9 10 and 15, the claims where amended to included the language, “is configured to” or “is also configured to.” It is not clear from the claims whether the connections actually occur or are simply the intended function of the various configurations.

13. Regarding claim 7, the Applicant has amended the specification to add a description for “line set.” That amendment appears to broaden the description of line set from a single item to multiple items however the Examiner is not sure. The confusion about what is now included within the line set causes this claim to be indefinite.

14. Regarding claims 9 and 10, the Applicant has amended the claims to more closely match the specification. In particular, page 142, lines 2 – 11 includes, “As described in previous

embodiments, a task or computer program, such as a listener task can be sent by the first central computer 109 to the user interface for the user interface 118' *to listen for medical information from the first central computer 109*. The first central computer 109 can also send a second task or computer program, such as a listener task, to the user interface 118' for the user interface 118' *to listen for medical information* from directly from the medical device 120.” (emphasis added)

The Examiner is unsure how a user interface “listens” for information. Neither the claims nor the specification define what the “medical information” is. The Examiner understands the amendment to mean that the user interface may receive instructions from a central computer.

Claim Rejections - 35 USC § 102

15. ***Claims 1 – 5, 9 – 18, 21, 24, 25, 27 – 30, 40, 46 – 49, 51 and 52*** are rejected under 35 U.S.C. 102(b) as being anticipated by Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568.

16. As per claim 1, Lebel teaches a multi-purpose user interface for a healthcare system having a medical device and a first central computer remote from the medical device, the medical device and the first central computer being separate from the multi-purpose user interface, the user interface comprising:

- A housing (figure 3, #34);
- A processor (figure 3, #42);
- A memory (figure 3, #42 and paragraph 202);
- A communications interface
 - For providing communication between the user interface and the medical device (figure 3, #56) and

- For providing communications between the user interface and the first central computer (figure 3, #94 and paragraph 159, IR communications link and further paragraphs 169, 202 and 203, second external device); and,
 - A display for displaying a medical prompt and for displaying medical information received from the first central computer (figure 3, #36).
17. As per claim 2, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is configured to connect to the medical device (paragraph 27, serial interface).
18. As per claim 3, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the medical device includes a controller (figure 3, #6).
19. As per claim 4, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to control the operation of the medical device (figure 3, #32).
20. As per claim 5, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the first central computer is structured to control the operation of the medical device (figure 3, #32).
21. As per claim 9, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the processor is configured to
- receive a plurality of executable instructions comprising a first listener task from the first central computer (paragraphs 202 and 203),

- which when executed by the processor, cause the user interface to listen for medical information from the first central computer (paragraph 203, parameter or programming updates and the devices operate on a loop).
- 22. As per claim 10, Lebel teaches the interface of claim 9 as described above. Lebel further teaches the interface wherein the processor is configured to
 - receive a plurality of executable instructions comprising a second listener task from the first central computer, which when executed by the processor, cause the user interface to listen for medical information from the medical device (paragraph 203).
- 23. As per claim 11, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the communications interface is a wireless communications interface for communicating with a wireless access point (paragraph 155).
- 24. As per claim 12, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to receive status information regarding the operation of the medical device, and display the status information on the display (paragraph 250).
- 25. As per claim 13, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the medical device is one of at least a volumetric infusion pump and a syringe pump (paragraph 152 or 206, syringe), and wherein the user interface is structured to program the medical device with at least one of an infusion rate, a volume to infuse, and a start time (paragraphs 3, 77, volume).
- 26. As per claim 14, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the medical prompt is an infusion prompt displayed on the display

of the user interface and wherein the infusion prompt comprises an infusion prompt for at least two channels controlled by the medical device (paragraph 204, where the displayed information represents non-functional descriptive information).

27. As per claim 15, Lebel teaches the interface of claim 2 as described above. Lebel further teaches the interface wherein the user interface is also configured to connect to a second medical device (paragraph 27, serial interface).

28. As per claim 16, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the communications interface also provides for communication between the user interface and a second medical device (paragraph 420).

29. As per claim 17, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the medical device is a pump controller (figure 3 and paragraph 334), and wherein the medical prompt displayed on the display of the user interface comprises a first infusion prompt for the pump controller and a second infusion prompt for a second pump controller (paragraph 138 and paragraph 420).

30. As per claim 18, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to display a selection prompt on the display for selecting at least one medical device to associate the user interface with (paragraph 222, setting operational state).

31. As per claim 21, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to receive the identification of at least one medical device to associate the user interface with (paragraph 142).

32. As per claim 24, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to send a request to the first central computer to locate an available and qualified clinician for the user interface (paragraph 177, alert).

33. As per claim 25, Lebel teaches the interface of claim 24 as described above. Lebel further teaches the interface wherein the first central computer sends a message to a clinician device that the user interface is in need of attention, and receives a response from the clinician device that the clinician will attend to the user interface (paragraph 159, emergency notification).

34. As per claim 27, Lebel teaches a healthcare system for use in a care-giving facility, comprising:

- A medical device (figure 3, implantable);
- A first central computer remote from the medical device (paragraphs 169, 202 and 203, second external device); and,
- A multi-purpose user interface separate from the medical device and the first central computer, the multi-purpose user interface (figure 3, #32) having
 - A housing (figure 3, #34),
 - A processor (figure 3, #42),
 - A memory (figure 3, #42 and paragraph 202),
 - A communications interface
 - For Providing communication between the user interface and the medical device (figure 3, #56)and

- For providing communications between the user interface and the first central computer (figure 3, #32), and
- A display for displaying a medical prompt and for displaying medical information received from the first central computer (figure 3, #36).

The Examiner understands the first central computer and the multi-purpose interface being the same device or a computer with a monitor.

35. As per claim 28, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system wherein the first central computer is a medical device server structured to utilize web services for communication with the medical device and to the user interface (paragraph 159).

36. As per claim 29, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system wherein the first central computer is structured to send a first script to the medical device to perform a first task (paragraph 161 and 162) and is structured to send a second script to the user interface to perform a second task (paragraph 161 and 162).

37. As per claim 30, Lebel teaches the system of claim 29 as described above. Lebel further teaches the system wherein the first and second tasks are one of at least a listen task, an alarm task, an alert task, a message task, a low battery task, an occlusion task, a pre-occlusion task, a bolus task, a KVO task, a STAT task, a change order task, a new order task, a lab result task, an MRI results task, an update task, a change in telemetry data task, a change in vital signs task, a doctor contact task, a patient contact task, a loss of communications task, a relay of message from other device task; and a new rate task (relay of message through sound and bolus).

38. As per claim 40, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system comprising:

- A plurality of wireless access points through which the medical device and the user interface communicate with the first central computer (paragraph 420, multiple implantable devices).

39. As per claim 46, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system comprising:

- A plurality of wireless access points for communication among the user interface, the medical device, and the first central computer (paragraph 420, multiple implantable devices).

40. As per claim 47, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system comprising a second medical device (paragraph 420), wherein the user interface housing is structured to provide for removable connection to the second medical device (figure 5, multiple serial connections).

41. As per claim 48, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system comprising:

- Wherein the medical device has an alarm/alert module that identifies the existence of at least one of an alarm or alert condition (paragraph 177),
- Wherein the first central computer is structured to receive a signal from the alarm/alert module or from the multi-purpose user interface relating to the alarm or alert condition (paragraph 177),

- The first central computer further having a timer module that sets a timer limit (paragraphs 27 – 40),
 - The multi-purpose user interface having a receiver that receives an alarm or alert condition signal from the first central computer or from the medical device (figure 1, #44),
 - Wherein the user interface is further structured to display text or an icon representative of the alarm/alert condition signal (the displayed information is non-functional descriptive information), and
 - To provide an audible alarm or alert representative of the received alarm/alert condition signal (figure 1, #44 and paragraph 202), and
 - Wherein the first central computer escalates the alarm or alert condition signal if no response to the alarm or alert condition signal is received from either the medical device or from the user interface within the timer limit (paragraph 276, where the system resets itself).
42. As per claim 49, Lebel teaches a method for operating a healthcare system within a care-giving facility, the system having a medical device, a first central computer remote from the medical device, and a multi-purpose user interface separate from the first central computer and the medical device, the method comprising the steps of:
- causing the first central computer to receive first medical data from the medical device (paragraph 203);
 - causing the first central computer to receive second medical data from the user interface (figure 1, #56, where multiple data is sent and paragraph 420, multiple pumps);

- causing the first central computer to send third medical data to the user interface (paragraph 203, parameter or programming updates and the devices operate on a loop);
- causing the first central computer to send a communication task to the user interface for providing at least one communication capability for communication between the medical device and the user interface (paragraphs 202 and 203); and
- causing the first central computer to send fourth medical data to the medical device, the fourth medical device comprising operating parameters for the medical device (paragraph 203).

43. As per claim 51, Lebel teaches a multi-purpose user interface for a healthcare system having a medical device and a first central computer remote from the medical device, the user interface being separate from the medical device and the first central computer, the user interface comprising:

- A housing (figure 3, #34);
- A processor (figure 3, #42);
- A memory (figure 3, #42 and paragraph 202);
- A communications interface for providing communications between the user interface and the first central computer (figure 3, #56); and,
- A display for displaying a medical prompt and for displaying medical information received from the first central computer (figure 3, #36),
 - Wherein the medical prompt requests input on directing the first central computer to send operating parameters to the medical device (paragraphs 188 – 192).

44. As per claim 52, Lebel teaches the user interface of claim 51 as described above. Lebel further teaches the user interface wherein the medical prompt is generated at the first central computer and sent to the display of the user interface from the first central computer (paragraph 132).

45. *Claims 54 and 57 – 64 are* rejected under 35 U.S.C. 102(b) as being anticipated by Blomquist, U.S. Pre-Grant Publication 2002/ 0029776.

46. As per claim 54, Blomquist teaches a system for monitoring healthcare data, comprising:

- A medication delivery pump for infusing a solution, the pump having a first location, the pump having first healthcare data associated therewith (figure 1, #110);
 - A vital signs monitor proximate the first location, the monitor having second healthcare data associated therewith (figure 1, #104 or paragraph 50, blood pressure monitor);
 - A central computer for receiving the first and second healthcare data (figure 1, #102);
- and,
- An interface device remote from the infusion pump and the vital signs monitor and in communication with the central computer, for displaying at least a portion of each of the first and second healthcare data on a single interface screen on the interface device (figure 3, control system).

47. As per claim 57, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the central computer manipulates the first and second healthcare data to combine at least the portion of each of the first and second healthcare data for use in displaying on the interface device (paragraph 98).

48. As per claim 58, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the first healthcare data comprises at least one of pump alarm data, pump alert data, medication being infused data, medication to be infused data, rate of infusion data, medication dose data, volume to be infused data, volume already infused data, volume left to be infused data, infusion time data, time left for infusion data, time elapsed for infusion data, order comparison data, limits data, patients with active infusions data, channels being used for pump data, location of pump data, pumps on standby data, pumps running data, pumps stopped data, and infusion near end alert data (paragraph 88, dosage).

49. As per claim 59, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the second healthcare data comprises at least one of vital signs data, arrhythmia data, hemodynamic data (paragraph 50, vital signs).

50. As per claim 60, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the medication delivery pump comprises at least one of a MEMS pump and an infusion pump (paragraph 2, pumps for infusing).

51. As per claim 61, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system

- Wherein the interface device further comprises options for programming and/or managing the pumps (paragraph 100),
- Wherein the options comprise at least one of clearing the volume infused at the end of a shift, silencing alarms and alerts, accessing documentation of titration history, accessing an eMAR, accessing clinical documentation, and accessing information on comparisons

of drug label, rate/dose, or concentration data programmed on infusion pump to a pre-defined list of high and low dose or concentration limits (paragraph 100, history).

52. As per claim 62, Blomquist teaches a method for monitoring healthcare data within a healthcare system, comprising the steps of:

- causing a central computer to receive first healthcare data associated with a medication delivery pump for infusing a solution, the pump having a first location (paragraphs 58 and 99);
- causing the central computer to receive second healthcare data associated with a patient monitor proximate the first location (paragraph 50 and 99); and,
- causing the central computer to combine at least a portion of each of the first and second healthcare data (paragraph 51 and 99);
- causing the central computer to send the combine first and second healthcare data to an interface device remote from the medication delivery pump and the patient monitor (paragraphs 99 – 102); and
- causing the interface device to display the combined first and second healthcare data on a single interface (paragraph 99 patient record and paragraph 103).

53. As per claim 64, Blomquist teaches the method of claim 62 as described above.

Blomquist further teaches the method the step of comprising causing the central computer to receive a request from the interface device, the request comprising at least one of a programming request and a management request (paragraph 55, programming).

54. **Claims 6 – 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of Olsen, U.S. Pre-Grant Publication 2002/ 0173774.

55. As per claim 6, Lebel teaches the interface of claim 1 as described above.

Lebel does not explicitly teach the interface wherein the medical device is a MEMS Pump (paragraph 205, other pump).

However, Olsen further teaches the interface wherein the medical device is a MEMS Pump (paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel

- The prior art differs from the claim by the substitution of some components. The substituted components were known. The technical ability existed to substitute the components as claimed and the result of the substitution is predictable.

56. As per claim 7, Lebel teaches the interface of claim 6 as described above.

Lebel further teaches the interface wherein the pump is integral with a line set (paragraph 117).

Lebel does not explicitly teach the interface wherein the MEMS pump is integral with a line set.

However, Olsen further teaches the interface wherein the MEMS pump is integral with a line set (paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel

- The prior art differs from the claim by the substitution of some components. The substituted components were known. The technical ability existed to substitute the components as claimed and the result of the substitution is predictable.

57. As per claim 8, Lebel teaches the interface of claim 6 as described above.

Lebel further teaches the interface wherein the MEMS pump comprises an identifier for identifying the MEMS pump to at least one of the first central server and the user interface (paragraph 157).

Lebel does not explicitly teach the interface wherein the MEMS pump comprises an identifier for identifying the MEMS pump to at least one of the first central server and the user interface.

However, Olsen further teaches the interface wherein the MEMS pump comprises an identifier for identifying the MEMS pump to at least one of the first central server and the user interface (paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel

- The prior art differs from the claim by the substitution of some components. The substituted components were known. The technical ability existed to substitute the components as claimed and the result of the substitution is predictable.

58. *Claims 19, 20, 22 and 23* are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568.

59. As per claim 19, Lebel teaches the interface of claim 18 as described above.

Lebel further teaches the interface wherein the at least one medical device is of a first type and another medical device is of a second type (paragraph 420).

Lebel does not explicitly teach the interface wherein the user interface is structured to operate in accordance with a first personality associated with the first type and is structured to operate in accordance with a second personality associated with the second type.

However, it would be a matter of prima facie obvious design choice to configure an interface wherein the user interface is structured to operate in accordance with a first personality associated with the first type and is structured to operate in accordance with a second personality associated with the second type.

60. As per claim 20, Lebel teaches the interface of claim 19 as described above. Lebel further teaches the interface wherein the first and second types are selected from a group consisting of an infusion pump personality, a syringe pump personality, and a pulse oximeter (paragraph 413).

61. As per claim 22, Lebel teaches the interface of claim 21 as described above. Lebel further teaches the interface wherein the at least one medical device is of a first type and another medical device is of a second type (paragraph 413 and 420).

Lebel does not explicitly teach the interface wherein the user interface is structured to operate in accordance with a first personality associated with the first type and is structured to operate in accordance with a second personality associated with the second type.

However, it would be a matter of prima facie obvious design choice to configure an interface wherein the user interface is structured to operate in accordance with a first personality

associated with the first type and is structured to operate in accordance with a second personality associated with the second type.

62. As per claim 23, Lebel teaches the interface of claim 22 as described above. Lebel further teaches the interface wherein the processor automatically programs the user interface to operate in accordance with the first type upon receipt of the identification of the at least one medical device (paragraph 203, closed loop).

63. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of McDevitt et al., U.S. Pre-Grant Publication 2003/ 0064422.

64. As per claim 26, Lebel teaches the interface of claim 1 as described above. Lebel does not explicitly teach the interface wherein at least a subset of communications sent and received by the communications interface are secure communications. However, McDevitt further teaches the interface wherein at least a subset of communications sent and received by the communications interface are secure communications (paragraph 432, encryption).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable. When combined, the elements perform the same function as they did separately.
- With the motivation to encrypt for security purposes (McDevitt paragraph 416).

65. *Claims 31 – 36, 39, 41, 43 and 44* are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of Blomquist, U.S. Pre-Grant Publication 2002/ 0029776.

66. As per claim 31, Lebel teaches the system of claim 27 as described above.

Lebel further teaches the system comprising

- The first central computer comprises a first database and a first functional feature set (paragraph 27),

Lebel does not explicitly teach the system comprising

- The healthcare system further comprising
 - A second central computer having a second database and a second functional feature set, and
 - Wherein the user interface can receive data from the second database relating to the second functional feature set of the second central computer through the first central computer.

However, Blomquist further teaches the system comprising

- The healthcare system further comprising
 - A second central computer having a second database and a second functional feature set (figure 1, #102 and #106), and
 - Wherein the user interface can receive data from the second database relating to the second functional feature set of the second central computer through the first central computer (figure 1, #108, Ethernet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable. When combined, the elements perform the same function as they did separately.
- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

67. As per claim 32, Lebel in view of Blomquist teaches the system of claim 31 as described above. Label further teaches the system wherein the first functional feature set comprises at least one of a volumetric infusion pump feature and a syringe pump feature (paragraph 152 or 206, syringe).

68. As per claim 33, Lebel in view of Blomquist teaches the system of claim 31 as described above. Label further teaches the system wherein the first functional feature set comprises at least one of a change pump channel feature, an administer infusion feature, a stop or discontinue infusion feature, a resume infusion feature, and a remove pump feature (paragraph 180, stop).

69. As per claim 34, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Lebel does not explicitly teach the system wherein the second functional feature set comprises at least one of a patient management feature, an item management feature, a facility management feature, a messaging feature, an alarms/alerts feature, a billing interface feature, a formulary interface feature, a lab results interface feature, an inventory tracking feature, a clinician

administration feature, an order entry feature, a pharmacy feature, a user interface feature, a user interface and clinician association feature, a volumetric infusion pump feature, and a syringe pump feature.

However, Blomquist further teaches the system wherein the second functional feature set comprises at least one of a patient management feature, an item management feature, a facility management feature, a messaging feature, an alarms/alerts feature, a billing interface feature, a formulary interface feature, a lab results interface feature, an inventory tracking feature, a clinician administration feature, an order entry feature, a pharmacy feature, a user interface feature, a user interface and clinician association feature, a volumetric infusion pump feature, and a syringe pump feature (paragraph 111 and figure 8, facility management with multiple pumps).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

70. As per claim 35, Lebel in view of Blomquist teaches the system of claim 31 as described above. Label further teaches the system wherein the first database comprises at least one of pump data, pump channel data, pump sub-channel data, order data, clinician data, patient data,

user interface data, medical device data, hub data, titration data, comparison data, alarm data, escalation data, hub alarm data, pump alarm data, channel alarm data, and alarm history data (paragraph 196, pump data).

71. As per claim 36, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label does not explicitly teach the system wherein the second database comprises at least one of patient management data, item management data, facility management data, messaging data, alarms/alerts data, inventory tracking data, clinician administration data, order entry data, user interface and clinician association data.

However, Blomquist further teaches the system wherein the second database comprises at least one of patient management data, item management data, facility management data, messaging data, alarms/alerts data, inventory tracking data, clinician administration data, order entry data, user interface and clinician association data (paragraph 111 and figure 8, facility management with multiple pumps).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.
When combined, the elements perform the same function as they did separately.
- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

72. As per claim 39, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label does not explicitly teach the system wherein the second central computer sends second data from the second database to the first central computer, wherein the first central computer combines the second data with first data from the first database, and wherein the first central computer sends the combined first and second data to the user interface for display on a display of the user interface.

However, Blomquist further teaches the system wherein the second central computer sends second data from the second database to the first central computer (paragraph 109, downloaded to the pump), wherein the first central computer combines the second data with first data from the first database (paragraph 109), and wherein the first central computer sends the combined first and second data to the user interface for display on a display of the user interface (paragraph 109).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

73. As per claim 41, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label does not explicitly teach the system wherein the first central computer receives second data from the second database in the second central computer for use in a validation procedure.

However, Blomquist further teaches the system wherein the first central computer receives second data from the second database in the second central computer for use in a validation procedure (paragraph 55, not corrupt).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

74. As per claim 43, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label does not explicitly teach the system wherein the first central computer is structured to receive patient order information from the second central computer and structured to receive medical device programming information from at least one of the medical device and the user interface, and wherein the first central computer is structured to compare the patient order information with the medical device programming information to determine if the medical

device programming information is accurate, and wherein the first central computer is structured to send a result of the comparison to at least one of the medical device and the user interface.

However, Blomquist further teaches the system wherein the first central computer is structured to receive patient order information from the second central computer and structured to receive medical device programming information from at least one of the medical device and the user interface, and wherein the first central computer is structured to compare the patient order information with the medical device programming information to determine if the medical device programming information is accurate, and wherein the first central computer is structured to send a result of the comparison to at least one of the medical device and the user interface (paragraph 109, where the design of the network is further a matter of prima facie design choice). It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

75. As per claim 44, Lebel in view of Blomquist teaches the system of claim 43 as described above.

Label does not explicitly teach the system wherein the result is sent from the first central computer to user interface to the medical device.

However, Blomquist further teaches the system wherein the result is sent from the first central computer to user interface to the medical device (paragraph 109).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

76. **Claims 37 and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of Blomquist, U.S. Pre-Grant Publication 2002/ 0029776 as applied above to claim 31, further in view of McDevitt et al., U.S. Pre-Grant Publication 2003/ 0064422.

77. As per claim 37, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label in view of Blomquist do not explicitly teach the system wherein the first central computer is operably connected to the second computer through a dedicated TCP/IP hard-wired connection.

However, McDevitt further teaches the system wherein the first central computer is operably connected to the second computer through a dedicated TCP/IP hard-wired connection (paragraph 430).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel in view of Blomquist. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel in view of Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to use an existing Internet protocol (McDevitt paragraph 426).

78. As per claim 45, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label in view of Blomquist do not explicitly teach the system wherein the first central computer is securely connected to the second computer, and wherein the medical device and the user interface do not communicate directly with the second central computer.

However, McDevitt further teaches the system wherein the first central computer is securely connected to the second computer (paragraph 442), and wherein the medical device and the user interface do not communicate directly with the second central computer (figure 66, network cloud verses a point to point direct connection).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel in view of Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Lebel in view of Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable. When combined, the elements perform the same function as they did separately.
- With the motivation to use an existing Internet protocol (McDevitt paragraph 426).

79. **Claim 42** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of Blomquist, U.S. Pre-Grant Publication 2002/ 0029776 as applied above to claim 41, further in view of Callahan et al., U.S. Pre-Grant Publication 2004/ 0029213.

80. As per claim 42, Lebel in view of Blomquist teaches the system of claim 41 as described above.

Label does not explicitly teach the system wherein the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

Blomquist further teaches the system wherein the validation procedure comprises the steps of determining whether the data expected to be received is received (paragraph 73).

Label in view of Blomquist do not explicitly teach the system wherein the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

However, Callahan further teaches the system wherein the validation procedure comprises the steps of receiving an XML document (figure 14 and paragraph 124, where the data is stored as

XML) and determining whether the data expected to be received from the XML document is received.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel in view of Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Lebel in view of Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

81. **Claim 53** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of DeLaHueraga, U.S. Pre-Grant Publication 2002/ 0116509.

82. As per claim 53, Lebel teaches the user interface of claim 52 as described above.

Lebel does not explicitly teach the user interface wherein the medical prompt is sent in the form of an html page and displayed on the display with a browser application running on the user interface.

However, DeLaHuerga further teaches the user interface wherein the medical prompt is sent in the form of an html page (paragraph 401) and displayed on the display with a browser application running on the user interface (paragraphs 401).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable. When combined, the elements perform the same function as they did separately.
- With the motivation to intelligibly receive a transmitted message and provide information contained therein to a browser for ultimate delivery to a server for storage or processing, a message receiving computer must be capable of translating the transmitted message into the language used by the server which is typically the hypertext markup language (DeLaHuerga, paragraph 32).

83. ***Claims 65, 66, 68 – 89, 90, 91 and 93 – 101 are*** rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist, U.S. Pre-Grant Publication 2002/ 0029776 in view of Martrucci et al., U.S. Pre-Grant Publication 2004/ 0104271.

84. As per claim 65, Blomquist teaches a system for tracking and reporting healthcare system data, comprising:

- A first medical pump having first medical pump data associated therewith (figure 1, #110);
- A second medical pump having second medical pump data associated therewith (figure 1, additional #110);
- A central computer in communication with the first and second medical pumps over a communications network, for receiving and storing the first and second medical pump data (figure 1, #102); and,
- an interface device remote from the first medical pump and the second medical pump having an interface screen for displaying a manipulated version of the first and second medical pump data (paragraph 99 patient record and paragraph 103),

Blomquist does not explicitly teach the system wherein

- wherein the manipulated version of the first and second medical pump data comprises near miss data for the first and second pumps.

However, Martrucci further teaches the system wherein

- wherein the manipulated version of the first and second medical pump data comprises near miss data for the first and second pumps (paragraph 35, incorrect programming).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

85. As per claim 66, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the central computer processes the first and second medical pump data to create the manipulated version of the first and second medical pump data by at least one of totalizing, calculating, combining, comparing, analyzing, computing, and tabulating the first and second medical pump data (figure 1, #106 and paragraph 117, combining).

86. As per claim 68, Blomquist in view of Martrucci teaches the system of claim 65 as described above.

Blomquist does not explicitly teach the system wherein the near miss data is sorted by medication.

However, Martrucci further teaches the system wherein the near miss data is sorted by medication (figure 32(b) where the separation or integration of data is a matter of design choice). It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

87. As per claim 69, Blomquist in view of Martrucci teaches the system of claim 65 as described above.

Blomquist does not explicitly teach the system wherein the manipulated version of the first and second medical pump data comprises at least one of near miss wrong drug data, near miss wrong time data, near miss wrong route data, near miss wrong dose data, and error wrong dose data.

However, Martrucci further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of near miss wrong drug data, near miss wrong time data, near miss wrong route data, near miss wrong dose data, and error wrong dose data (paragraph 35, wrong drug data).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

88. As per claim 70, Blomquist in view of Martrucci teaches the system of claim 69 as described above.

Blomquist does not explicitly teach the system wherein the manipulated version of the first and second medical pump data is broken down by at least one of unit, infusion, non-infusion and medication.

However, the storage of data within a database represents prima facie obvious design choice to make the data separable or integral.

89. As per claim 71, Blomquist in view of Martrucci teaches the system of claim 70 as described above.

Blomquist further teaches the system

- Wherein the central computer is further provided for receiving and storing first non-pump medication delivery data and second non-pump medication delivery data (paragraph 107 where the data represents non-functional descriptive information. The storing of data within a database represents prima facie design choice),
- Wherein the interface device is further provided for displaying a manipulated version of the first and second non-pump medication delivery data (paragraph 106, where the displayed data represents non-functional descriptive information), and
- Wherein the manipulated version of the first and second non-pump medication delivery data is sorted by hospital unit and totalized with the manipulated version of the first and second medical pump data (paragraph 107, the storage of data within a database represents prima facie obvious design choice to make the data separable or integral).

90. As per claim 72, Blomquist in view of Martrucci teaches the system of claim 69 as described above.

Blomquist does not explicitly teach the system wherein near miss wrong time comprises at least one of late delivery, early delivery, and missed delivery.

However, Martrucci further teaches the system wherein near miss wrong time comprises at least one of late delivery, early delivery, and missed delivery (figure 15(i), late delivery).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

91. As per claim 73, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of scan error data, source of scan data, scan type data (item or patient), expected scan data, and actual scan data (paragraph 107, where the data represents non-functional descriptive information).

92. As per claim 74, Blomquist in view of Martrucci teaches the system of claim 65 as described above.

Bloomquist does not explicitly teach the system wherein the interface device comprises a second interface screen for selecting criteria to display the manipulated version of the first and second medical pump data.

However, the design of the computer display is a matter of prima facie obvious design choice.

93. As per claim 75, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of total administrations data, total wrong time data, reason data, medication data, patient data, order data, order administration time data, administration time data, early medication data, late medication data, expired medication

data, and missed medication data (paragraph 107, medication data where the data represents non-functional descriptive information).

94. As per claim 76, Blomquist in view of Martrucci teaches the system of claim 75 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is sorted by at least one of unit, infusion, non-infusion, nurse, and medication.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

95. As per claim 77, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of infusions data, matches data, resolved mismatches data, accepted mismatches data, and no comparisons data (paragraph 107, infusion data).

96. As per claim 78, Blomquist in view of Martrucci teaches the system of claim 77 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is sorted by at least one of type of infusion and unit.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

97. As per claim 79, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of no match data, match data, and no comparison data (paragraph 107, where match data is the infusion data).

98. As per claim 80, Blomquist in view of Martrucci teaches the system of claim 79 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is sorted by at least one of infusion type, medication type, volume, infusion route, total, unit, primary and piggyback.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

99. As per claim 81, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of infusions data, rate matches data, rate resolved mismatches data, rate accepted mismatches data, rate no comparisons data, mode mismatches data (paragraph 107, infusion data).

100. As per claim 82, Blomquist in view of Martrucci teaches the system of claim 81 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is sorted by at least one of unit, mode, medication, and patient.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

101. As per claim 83, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of unit data, patient data, nurse data, order data, administration data, occurrence data date, pump mode data, pump status data, rate data, comparison data, and dose data (paragraph 107, patient data).

102. As per claim 84, Blomquist in view of Martrucci teaches the system of claim 83 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is sorted by at least one of unit, patient, nurse, order, and administration.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

103. As per claim 85, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of infusion data, alert data, reprogramming after alert data, accepted alert override data, and label data (paragraph 107, infusion data).

104. As per claim 86, Blomquist in view of Martrucci teaches the system of claim 85 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is sorted by at least one of unit and label.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

105. As per claim 87, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of infusion data, KVO alert data, alarm data, alarm by code data, alarm by device data, alert by code data, alert by device data, alarm code data, alert code data, escalation data, escalation level data, patient data, nurse data, order data, source data, device data, mode data, occurrence data, cleared time data, silenced time data, response time data, alarm condition data, mode data, and medication data (paragraph 107, infusion data).

106. As per claim 88, Blomquist in view of Martrucci teaches the system of claim 87 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is sorted by at least one of unit, alarm condition, alert condition, alarm code, alert code, patient, nurse, order, occurrence time, and medication.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

107. As per claim 89, Blomquist in view of Martrucci teaches the system of claim 65 as described above. Blomquist further teaches the system wherein the interface device is a pharmacist interface device (paragraph 111), and wherein the manipulated version comprises at least one of pump status data for all connected pumps in a unit, pump status data for all connected pumps in a hospital, pump status data for all connected pumps which are active in the unit, pump status data for all connected pumps which are active in the hospital (paragraphs 57 – 69 and paragraph 81, 82).

108. As per claim 90, Blomquist teaches a system for tracking and reporting healthcare system data, comprising:

- A plurality of interface devices, at least one of the interface devices having a receiver for receiving identifier data (figure 1); and,
- A central computer in communication with the plurality of interface devices over a communications network, for receiving and storing the identifier data (figure 1, #102),
 - Wherein at least one of the plurality of interface devices has an interface screen for displaying a manipulated version of the identifier data (figure 1, #104),

Blomquist does not explicitly teach the system

- Wherein the manipulated version of the identifier data comprises near miss data relating to the use of the identifier data.

However, Martrucci further teaches the system

- Wherein the manipulated version of the identifier data comprises near miss data relating to the use of the identifier data (paragraph 35, incorrect programming).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

109. As per claim 91, Blomquist in view of Martrucci teaches the system of claim 90 as described above. Blomquist further teaches the system wherein the central computer processes the identifier data to create the manipulated version of the identifier data by at least one of totalizing, calculating, combining, comparing, analyzing, computing, and tabulating the identifier data or the use thereof in delivering medication (figure 1, #106 and paragraph 117, combining).

110. As per claim 93, Bloomquist teaches the system of claim 92 as described above. Bloomquist does not explicitly teach the system wherein the manipulated data is broken down by at least one of unit, infusion, non-infusion, and medication.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

111. As per claim 94, Blomquist in view of Martrucci teaches the system of claim 90 as described above.

Blomquist does not explicitly teach the system wherein the manipulated version of the identifier data comprises at least one of near miss wrong drug data, near miss wrong time data, near miss wrong route data, near miss wrong dose data, and error wrong dose data.

However, Martrucci further teaches the system wherein the manipulated version of the identifier data comprises at least one of near miss wrong drug data, near miss wrong time data, near miss wrong route data, near miss wrong dose data, and error wrong dose data (paragraph 35, wrong drug data).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

112. As per claim 95, Bloomquist teaches the system of claim 90 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version of the identifier data is broken down by hospital unit and totalized.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

113. As per claim 96, Blomquist in view of Martrucci teaches the system of claim 91 as described above. Blomquist further teaches the system comprising:

- A first medical pump having first medical pump data associated therewith (figure 1);
- A second medical pump having second medical pump data associated therewith (figure 1),
 - Wherein the central computer is in communication with the first and second medical pumps over the communications network, for receiving and storing the first and second medical pump data (figure 1, #102),
 - Wherein the at least one interface device having an interface screen for displaying a manipulated version of the first and second medical pump data and the manipulated version of the identifier data by hospital unit and totaled together (figure 1, #102 or #104, figure 2 and paragraph 40).

114. As per claim 97, Blomquist in view of Martrucci teaches the system of claim 90 as described above. Blomquist further teaches the system wherein the manipulated version of the identifier data comprises at least one of scan error data, source of scan data, scan type data (item or patient), expected scan data, and actual scan data (paragraph 107, where the data represents non-functional descriptive information).

115. As per claim 98, Blomquist teaches the system of claim 90 as described above. Blomquist does not explicitly teach the system wherein the interface device comprises a second interface screen for selecting criteria to display the manipulated version of the identifier data. However, the design of the computer display is a matter of prima facie obvious design choice.

116. As per claim 99, Blomquist in view of Martrucci teaches the system of claim 90 as described above. Blomquist further teaches the system wherein the criteria comprises at least one of time, date, device, unit, screen, bar code type, screen type, user group, and user (paragraph 96, bar code).

117. As per claim 100, Blomquist in view of Martrucci teaches the system of claim 90 as described above. Blomquist further teaches the system wherein the manipulated version of the identifier data comprises at least one of total administrations data, total wrong time data, reason data, medication data, patient data, order data, order administration time data, administration time data, early medication data, late medication data, expired medication data, and missed medication data (paragraph 96, medication data where the data represents non-functional descriptive information).

118. As per claim 101, Bloomquist teaches the system of claim 100 as described above. Bloomquist does not explicitly teach the system wherein the manipulated version is broken down by at least one of unit, infusion, non-infusion, nurse, and medication. However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

Response to Arguments

119. Applicant's arguments, see objection regarding written description, filed 6/16/2009, with respect to claim 38 have been fully considered and are persuasive. The objection of claim 38 has been withdrawn.

120. Applicant's arguments, see objection regarding informalities, filed 6/16/2009, with respect to claim 59 have been fully considered and are persuasive. The objection of claim 59 has been withdrawn.

121. Applicant's arguments, see objection regarding 35 U.S.C. 112, 2nd paragraph rejection, filed 6/16/2009, with respect to claims 3 and 9 have been fully considered and are persuasive. The 35 U.S.C. 112, 2nd paragraph rejection of claims 3 and 9 has been withdrawn.

122. Applicant's arguments, see 35 U.S.C. 112, 2nd paragraph rejection, filed 6/16/2009, with respect to the rejection(s) of claim(s) 2 and 15 under 35 U.S.C. 112, 2nd paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of as detailed above.

123. Applicant's arguments filed 6/16/2009 have been fully considered but they are not persuasive.

- Regarding the priority claim. The Examiner has expanded upon the priority concerns as detailed above.
- Regarding the objection to the drawings regarding "line set." The Examiner is unsure whether the Applicant has added new matter with the added description or whether the description is simply unclear. The Examiner believes that it is unclear and therefore has added an updated rejection above to the drawing objection.
- Regarding the 35 U.S.C. 101 rejection to claims 49, 50, 62 and 64, please see the updated rejection above.
- Regarding the 35 U.S.C. 102(b) rejections of claims 1 – 5, 9, 18, 21, 24, 25, 27 – 30, 40, 46 – 52, the Applicant states, "Lebel does not disclose a processor or computer

independent of the external device 32 and the implantable device 2 that communicates with the external device.” Please see the updated rejections above.

- Regarding the 35 U.S.C. 102(b) rejections of claims 54 - 64, the Applicant states, “Bloomquist does not disclose or suggest sending data from such a data-gathering device to a central computer and displaying at least a portion of the data on a single display of an interface device along with data from the pump.” The Examiner notes that this statement differs from the claim language. In addition, the claims do not require that the data be displayed on the computer. Regardless, please see the updated rejections above.
- Applicant's arguments with respect to claims 65 - 101 have been considered but are moot in view of the new ground(s) of rejection. Within the independent claims, the Applicant has included descriptions of the data as “near miss data.” The Examiner feels that this is nonfunctional descriptive information however, the rejection has been changed to a 103 as described above.

Conclusion

124. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Agency for Healthcare Research and Quality, “Making Healthcare Safer” July, 2001

125. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/N. R. S./
Examiner, Art Unit 3626
9/8/2009

/Robert Morgan/
Primary Examiner, Art Unit 3626